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TITLE: Hormone Receptors in Breast Cancer Prognosis - Racial and Quantitative Effects

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in African Americans and Whites a	and determines whether survival	effects differ between	the two group	s. This study also assesses
whether a dose-response relationsh	ip, linear or nonlinear, exists be	tween hormone recepto	ors and surviva	l. Findings of this study may
lead to better prediction of survival	and to identification of subsets	of patients at higher ri	sk that may ha	ve gone unrecognized by the
application of a single cutpoint. Ou	ır preliminary findings indicate	that African American	breast cancer	patients have more estrogen
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INTRODUCTION

Breast cancer survivors compose the largest group of cancer survivors in the United States today. As considerable heterogeneity exists within stages and between racial/ethnic groups in breast cancer survival, it is important to develop a better understanding of prognostic factors. Estrogen and progesterone receptors in breast tumor tissue are regarded to be one of the more important prognostic factors in breast cancer patients. However, currently in clinical practice hormone receptor status is treated as either being present or absent and is treated similarly in all racial/ethnic groups. The dichotomization of hormone status may lead to loss of valuable information and hormone receptor status may not have the same effect in African Americans and whites. This historical cohort study evaluates quantitative differences in estrogen and progesterone receptors in the breast tumors of African Americans and Whites and determines whether survival effects differ between the two groups. This study will also assess whether a doseresponse relationship, linear or nonlinear, exists between quantitatively assessed hormone receptors and survival, as opposed to the currently popular dichotomized assessment of receptor status. Findings of this study may lead to better prediction of survival and to identification of subsets of patients needing particular clinical attention that may have gone unrecognized by applying a single cutpoint to all patients.

BODY

Year two of this three-year study has been completed and the items in the Statement of Work that should have been undertaken and/or completed are summarized in Table 1.

Table 1. Progress on items in the *Statement of Works* (Changes from the 2001 annual report are in **bold face type.**)

	Description	Planned time	Progress
Task 1	Initial establishment of study team, approach and issues	1 to 4 months	Completed
	Staff training	1 to 4 months	Completed
	Preparation of computer programs and study database	1 to 4 months	Completed
Task 2	Establish and Characterize Cohort	4 to 8 months	Completed
	Abstraction of Patient / Tumor Data From	4 to 28 months	
	Hormone receptor log book data		Computer entry completed
	Medical record abstraction		815 patients completed (~85%)
	Construction of computer entry system for record	:	Microsoft Access database
	abstracted data		entry forms written
	Data entry into computer databases		Records for 114 individuals
			have been entered
Task 3	SES estimates based on 1990 US Census data	12 to 28 months	Continuing
Task 4	Survival Data Collection From		
	Henry Ford Health System Tumor Registry	12 to 28 months	Initial completed, ongoing
	SEER	18 to 28 months	Initial completed, ongoing
	Michigan Death Index	18 to 28 months	Initial completed, ongoing
Task 5	Attend breast cancer conference	Year two	1 Attended / DoD upcoming

The current study staff consists of the following:

Project Staff

C. Martin Tammemagi – Principal Investigator
Chris Neslund-Dudas – Project Manager
Mary Ellen Frebes – Tumor registrar and quality assurance audits
Jonathon Mitchell- Database manager/programmer
Rick Krajenta – Programmer/ tumor registry data specialist

Medical Record Abstractors (Coordinator Ms. Cheryl Spoutz)
Roseanne Rose
Karen Gerula
Mary Beland
Kay McGlynn

<u>Data Entry</u> Roseanne Rose Kim Beney Joan Broderick Barbara Harkness

Ms. Christine Neslund-Dudas, an Epidemiologist I, is helping manage the study, Mr. Richard Krajenta is in charge of the computer databases and data preparation, and Ms. Cheryl Spoutz heads a team of research abstractors who have a minimum of a two-year college degree in Health Information Management (HIM), have passed National Accreditation Examinations and are credentialed Registered Health Information Technicians (RHIT).

In year two of this study approximately 815 patient records were requested, obtained and abstracted. Incomplete or no records were obtained for 130 individuals after three repeat attempts. We are making vigorous efforts to locate these records.

Ms. Mary Ellen Frebes has joined the study in the last year. She is a certified tumor registrar (National Cancer Registrars Association) with 15 years of experience and is also a RHIT. Her role is to assure the quality of all vital statistics and staging data. She reviews each patient's completed abstract form and verifies all questionable data and

completes incomplete data by accessing data in the Henry Ford Health System (HFHS)

Tumor Registry, the Surveillance, Epidemiology and End Results (SEER) Tumor Registry

and the Social Security Death Index. Dr. Tammemagi also reviews each completed

abstraction form for completeness and consistency. Currently, Dr. Tammemagi is carrying

out all statistical analyses.

Jonathon Mitchell, a computer programmer, has written computer data entry forms using Microsoft Access. A representative sampling is presented in Appendix 1. The initial beta version has been tested and upgraded to the mature product in current use. A team of four data entry personnel has been trained. The reliability and accuracy of data entry was evaluated initial and will be re-evaluated at regular intervals. To date, the abstracted data of 114 patients have been entered into the computer database.

The study staff meets biweekly to discuss any issues, problems or concerns. Dr. Tammemagi or Ms. Neslund-Dudas is available to all staff to provide immediate responses to problems as they arise.

All available estrogen and progesterone hormone receptor data for breast cancer patients have been manually transcribed from the laboratory notebooks of the Department of Clinical Biochemistry into a Microsoft Access database. Information pertinent to this study was extracted from the HFHS Tumor Registry and was placed into another Microsoft Access file. Survival data has been collected from the HFHS Tumor Registry. Survival and other relevant clinicopathologic data have been collected from the Detroit SEER Tumor Registry. Also, death data for the breast cancer cohort has been downloaded from the Michigan Death Registry files and includes deaths up until the year 1999.

Socioeconomic status (SES) data was estimated for breast cancer patients in the HFHS Tumor Registry based on patient's address at diagnosis and the block group

medium household income (BGMHI) derived from the 1990 US Census. So far we have obtained SES estimates for approximately 70% of individuals, which is below what we have obtained in several past studies. We are currently assessing updated versions of MapMarker® and MapInfo® geocoding programs useful in providing census-based aggregate estimates of SES. It is anticipated that these programs will provide more complete data as well as a wider range of SES estimators.

We are on track to having all data collection and clean up completed by fall of 2002, whence analysis will begin. Statistical analysis, writing of manuscripts and dissemination of study results are expected to be completed by the end of the third study year, as planned.

This year Dr. Tammemagi attended and presented the following:

Tammemagi CM, C. Neslund-Dudas, M. Simoff, P. Kvale. Comorbidity explains some of the race difference in lung cancer survival. National Institutes of Health / American Cancer Society's Cancer Survivorship: Resilience across the lifespan. June 2, 2002, Washington, D.C.

Although these findings concerns lung cancer survival, they deal with a topic pertinent to the current study of racial/ethnic differences in breast cancer survival. Valid survival studies must take into consideration the effects of important prognostic factors in addition to the one under study. We have recently shown that comorbidity is the third most important predictor of survival in lung cancer patients, following stage and treatment, and it in part explains some of the racial/ethnic difference in lung cancer survival (Appendix 2). We have augmented the data collection procedures for this study to include comorbidity data to make possible assessment and adjustment for comorbidity (Appendix 3).

Dr. Tammemagi will be attending the Era of Hope meeting in September 2002.

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REPORTABLE OUTCOMES: NA.

CONCLUSIONS

It is too early into the study to draw any substantive or methodologic conclusions.

APPENDIX 1. Sample of Computer Database Entry Forms (Microsoft Access)

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JFCC - Hormone Receptors & Breast Cancer Survival Abstraction Form, V. Feb. 27, 2002

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(7) DISEASES OF THE CIRCULATORY SYSTEM (ICD 390-459)

CM99-If yes, specify 0 = No, 1 = Yes 0 = No, 1 = YesCM100-How long ago was most recent MI? - months CM100-How long ago was most recent MI? - years 0 = No, 1 = Yes0 = No, 1 = Yes0 = No, 1 = Yes0 = No, 1 = Yes CM97-Peri-, endo-, and myocarditis, cardiomyopathy (except that caused by tuberculosis or ST CM115D-Aortic, peripheral, visceral artery neourysms - Was it surgically corrected CM115B-Aortic, peripheral, visceral artery aneurysms - If yes, where was it locate CM115C-Aortic, peripheral, visceral artery aneurysms - What was its size? ___ c 0 = No, 1 = Yes0 = No, 1 = Yes 0 = No, 1 = Yes0 = No, 1 = Yes0 = No, t = Yes0 = No, 1 = Yes0 = No, 1 = Yes0 = No, 1 = Yes 0 = No, 1 = Yes 0 = No, 1 = Yes 0 = No, 1 = Yes0 = No, 1 = Yes0 = No, 1 = Yes CM102-Angina (non-specific or non-angina chest pain is coded under #322 CM113-Late effects of cerebrovascular disease, i.e., plegia or hemiplegi CM99-Hypertension with complications and secondary hypertensio 0 = No, 1 = Yes0 = No, t = Yes0 = No, 1 = YesCM116-Aortic and peripheral arterial embolism or thrombo CM101-Coronary atherosclerosis and other heart diseas CM117-Other circulatory disease, including hypertensio CM118-Phiebitis, thrombophiebitis and thromboembolis CM112-Transient cerebral Ischemi CM111-Other and ill-defined cerebrovascular diseas CM115-Aortic, peripheral, visceral artery aneurysm CM110-Occlusion or stenosis of precerebral arterie CM103-Pulmonary heart disease (cor pulmonal CM114-Peripheral and visceral atherosclerosi CM107-Cardiac arrest or ventricular fibrillatio CM106-Cardiac dysrhythmias/ arrhythmia CM119-Varicose veins of lower extremit CM104-Other or ill-defined heart diseas CM109-Acute cerebrovascular disease CM108-Congestive heart failur CM98-Essential hypertensio CM96-Heart valve disorders CM105-Conduction disorder CM100-Myocardial infractio

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CM121-Other diseases of veins and lymphatic

CM120-Hemorrhoid

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(14) CONGENITAL ANOMALIES (ICD 740-759)

CM213-Cardiac and circulatory anomalie

CM214-Digestive congenital anomalie

CM215-Genitourinary congenital anomalie

CM216-Nervous system congenital anomalie

CM217-Other congenital anomalie

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JFCC - Hormone Receptors & Breast Cancer Survival

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CM135-Intestinal infectio	0 = No. 1 = Yes	88 /		では、おきない。
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CM137-Diseases of mouth, excluding denta	0 = No, 1 = Yes	Yes		
CM138-Esophageal disorder		Xes		
CM139-Gastroduodenal ulcer (except hemorrhage	0 = No, 1 =	1 = Yes		
CM140-Gastritis and duodeniti	0 = No, T = Yes	Yes		
CM141-Other disorders of stomach and duodenu	0 = No, 1 = Yes	Yes		
CM142-Appendicitis and other appendiceal conditions	0 = No, 1 = Yes	Yes		
CM143-Abdominal herni $0 = No, 1 = Yes$		CM143-If yes, was it accompanied by obstruction or gangrene?	The state of the s	0 = No, 1 = Yes
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CM146-Diverticulosis and diverticuliti	N = 0	0 = No, 1 = Yes		
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CM152-Pancreatic disorders (not diabetes	0 = No, 1 = Yes			
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		,

No = 0 the default, YES = 1 No = 0, Yes = 7 Is this a recent infection (< 3 years old) or an active infection under treatment? No = 0, Yes = 7	・ 1、1の1の1の1の1の1の1の1の1の1の1の1の1の1の1の1の1の1の1	《《《··································		《水水水经验》(1997年),1997年	No = 0, Yes =1 Hepatitis virus: A,B,C,D,E,G, or othe 3=0, 7=8, 2=C, 3=D, 4=E, 5=G,	26		No = 0, Yes =1	No = 0, Yes =1 If yes, specify immunizatio		
(1) INFECTIOUS AND PARASITIC DISEASES (ICD 001-139) CM1 Tuberculosis No = 0, Yes = 1	CM2 Septicemia (except in labor) No = 0, Yes = 1	CM3 Bacterial infection, unspecified site	CM4 Mycoses	CM5 HIV infection/AIDS No = 0, Yes = 1	CM6 Hepatitis (infectious, not primarily alcohol-related, see #150)	CM7 Viral infection (not hepatitis)	CM8 Other infections, including parasitic	CM9 Sexually transmitted infections = STD (not HIV or hepatitis)	CM10 Immunizations and screening for infectious disease	CM248 Gangrene No = 0, Yes = 1	

Next

Back

	StudyID 03673810	The second secon
ist all medications taken by the pa	tient for 3 years prior to the breast cancer diagnosis.	
the oral contraceptives hormone rep	lacement therapies listed previously.	
Medication	Indication why it was given	Estimate usage 1 = Short term (< 6 months 2 = Long term (>= 6 month 9 = unknown)
ALDACTAZIDE	HTN	2 page 25 2 page
ZYLOPRIM	9	2
NALFON	KNEE PAIN	
CLINORIL	BURSITIS	<u> </u>
NAPROSYN	JOINT PAIN	
Language program acceptance of the control of the c		

er Survival Abstraction Form, V. Feb. 27, 2002	StudyID DAGFORID)D (ICD 760-779)		0 = No, 7 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes		0 = No, 1 = Yes	0 = No, T = Yes	Next		
JFCC - Hormone Receptors & Breast Cancer Survival		(15) CERTAIN CONDITIONS ORIGINATING IN THE PERINATAL PERIOD (ICD 760-779)	CM218-Liveborn	CM219-Short gestation, low birth weight, and fetal growth retardatio	CM220-Intrauterine hypoxia and birth asphyxi	CM221-Respiratory distress syndrom	CM222-Hemolytic jaundice and perinatal jaundic	CM223-Birth traum	CM224-Other perinatal condition	Back Back		

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(8) DISEASES OF THE RESPIRATORY SYSTEM (ICD 460-519)	-519)	医脱氧甲状腺 医多克氏试验检 化二氯甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基
CM122-Pneumonia (except that caused by tuberculosis or sexually transmitted diseas	or sexually transmitted diseas	0 = No, f = Yes
CM123-Influenza	0 = No, 1 = Yes	
CM124-Acute and chronic tonsilitis	0 = No, 1 = Yes	
CM125-Acute bronchitis	0 = No, 1 = Yes	
CM126-Other upper respiratory infection	0 = No, 1 = Yes	CM126-If yes, specify.
CM127-Chronic obstructive pulmonary disease bronchiectasi	ictasi $0 = No, 1 = Yes$	
CM127B-COPD otherwise not specifie	0 = No, 1 = Yes	
CM127C-Emphysem	0 = No, 1 = Yes	
CM127D-Chronic bronchiti	0 = No, 1 = Yes	
CM127E-Bronchiectasis	0 = No, 1 = Yes	
CM128-Asthm 0 = No, 1 = Yes		
CM304-Pulmonary fibrosis/intestinal lung disease	0 = No, 1 = Yes	
CM129-Aspiration pneumonitis, food/vomitu	0 = No, 1 = Yes	
CM130-Pleurisy, pneumothorax, pulmonary collapse (ate	e (atelectasi 0 = No, 1 = Yes	
CM131-Respiratory failure, insufficiency, arrest (adul	0 = No, 1 = Yes	S
CM132-Lung Disease due to external agents, including p	oneumoconioses, e.g., anthracosis, silic	CM132-Lung Disease due to external agents, including pneumoconioses, e.g., anthracosis, silicosis, asbestosis, berylliosis, siderosis, stannosis, barito
CM133-Other lower respiratory diseas	0 = No, 1 = Yes	
CM134-Other upper respiratory diseas	0 ≒ No, 1 = Yes	
	Back	Next

002						
, V. Feb. 27, 2						
Abstraction Form, V. Feb. 27, 2002		0 = No, 7 = Yes 0 = No, 7 = Yes	0 = No, 1 = Yes 0 = No, 1 = Yes			
	DREFARIT			Next		
ors & Breast Cancer Survival	StudyID (12) DISEASES OF THE SKIN AND SUBCUTANEOUS TISSUE (ICD 680-709)	ulitis or abscess		Back		
ırs & Breas	UTANEOUS TISS	infections, e.g., celluitits or abscess of ski				
ne Recepto	SKIN AND SUBC	s tissue	of skin order			
FCC - Hormone Recept	EASES OF THE	CM197-Skin and subcutaneous tissue CM198-Other inflammatory condition o	CM199-Chronic ulcer of skin CM200-Other skin disorder			
JFCC	(12) DIS	OM16	CM1			

APPENDIX 2.

Comorbidity Explains Some of the Race Difference in Lung Cancer Survival

C. M. Tammemagi, C. Neslund-Dudas, M. Simoff, P. Kvale Josephine Ford Cancer Center, Detroit, MI 48202

BACKGROUND

Lung cancer, the commonest cause of cancer death in North America, generally has a grave prognosis, which is worse in Blacks compared to Whites. The purpose of this study was to determine whether comorbidity explains some of the race difference in survival.

METHODS

A historical cohort study was carried out of 1155 lung cancer patients diagnosed at the Henry Ford Health System (HFHS) between 1995 and 1998. Sociodemographic, exposure, clinicopathologic, treatment and survival data were collected by abstraction of medical records and from the HFHS Tumor Registry. Fifty-six comorbidities were studied.

RESULTS

19 comorbidities were associated with survival: HIV/AIDS, tuberculosis, previous metastatic cancer, thyroid/glandular diseases, electrolyte imbalance, anemia, other blood diseases, dementia, neurologic disease, congestive heart failure, chronic obstructive pulmonary disease, asthma, pulmonary fibrosis, liver disease, gastrointestinal bleeding, renal disease, connective tissue disease, osteoporosis and peripheral vascular disease. Only the latter was protective. The occurrence of at least one of the 18 deleterious comorbidities occurred in 64.0% of women and 59.9% of men (p = 0.16), and 65.4% of Blacks and 59.0% of Whites (p = 0.03). The unadjusted hazard ratio for race (Black vs. White) was 1.203 (95% CI 1.05-1.38, p = 0.008) and adjusted for all 19 predictive comorbidities was 1.156 (95% CI 1.00-1.33, p = 0.05), a decline of 23.1%.

CONCLUSION

The higher prevalence of deleterious comorbidities in Blacks explains some of their overall poorer lung cancer survival.

APPENDIX 3. Revised Abstraction Form

JFCC -- Hormone Receptors & Breast Cancer Survival Abstraction Form, V. February 27, 2002 Study ID #: Abstraction Date: / / Abstraction Time: (use month/day/ year throughout) Abstractor ID: CASE DESCRIPTION & EPIDEMIOLOGIC DATA CONFIRMATION OF CASE STATUS Is there evidence in the chart that the patient was If Yes→ Continue. diagnosed with breast cancer or suspicion of Record original JFCC dx date here: ___/__/___ invasive breast cancer on the same date (or within 2 weeks of the date) as it appears as the "Diagnosis If No → Do alternative breast cancer diagnosis dates exist? Date" for the Josephine Ford Cancer Registry? Please enter the dates here: 1. ___/__________ 2. ___/__/_______ If you are unable to confirm diagnosis of invasive breast cancer, STOP REVIEW and consult with investigator. (Complete only if it differs from that provided, i.e., JFCC Tumor Registry data) SOCIODEMOGRAPHIC DATA First: Middle Initial: Name Last: Address at diagnosis: Street Address City State ZIP Code Current address, if different from diagnosis address Street Address City State ZIP Code Date of Birth: 4 = AsianRace 5 = Pacific Islander or Native Hawaiian 1 = White2 = Black / African American 6= Other, specify 3 = American Indian or Alaskan Native 9 = UnknownEthnicity 0= Non-Hispanic 1 = HispanicMarital Status at diagnosis 1= Married or living as married

2 = Not married

9= Unknown

2a = Single (never married)

2c = Widowed

2b = Divorced or legally separated

JFCC -- Hormone Receptors & Breast Cancer Survival Abstraction Form, V. February 27, 2002

BODY SIZE INFORMATION (exclude data during pregnancy) Date: / / Maximum Height (inches): ______ Date: ___/ ___/ Pre-diagnosis weight closest to diagnosis date (pounds): **REPRODUCTIVE / ENDOCRINE HISTORY** (Mark NA if data are not available) Age at menarche (years) Menopausal status at diagnosis. 01= Pre-menopausal 02= Peri-menopausal (Transition between pre- & post-menopause. Menstrual cycles irregular, hot flashes.) 03= Post-menopausal When did menopause occur? ______Year/age/years ago? 04= Hysterectomy. Number of ovaries removed? ______Date of surgery: ___/______ 99=Undetermined Parity (# of live births) as of the diagnosis date. If pre-menopausal, record the number of post-diagnosis live births 0=No 1=Yes 9=Unknown Did the patient use <u>hormone contraceptives?</u> Start date of use: ___/__/____ Type: 1=Birth Control Pills Length of time (years): 2=Shots or Injections Product Name: _____/ ____/ _____ 3=Subdermal Implants Type: 1=Birth Control Pills Length of time (years): 2=Shots or Injections Product Name: 3=Subdermal Implants Start date of use: ___/__/___/ Type: 1=Birth Control Pills Length of time (years): 2=Shots or Injections Product Name: 3=Subdermal Implants Did the patient use hormone replacement therapy? 0=No 1=Yes 9=Unknown Start date of use: ___/__/____ 1=Estrogen Alone Length of time (years): 2=Estrogen plus Progesterone Product Name: 3=Progesterone Alone 4=Other Start date of use: ___/__/___/ 1=Estrogen Alone Length of time (years): 2=Estrogen plus Progesterone Product Name: 3=Progesterone Alone 4=Other Start date of use: / / 1=Estrogen Alone Length of time (years): 2=Estrogen plus Progesterone Product Name: 3=Progesterone Alone 4=Other

JFCC -- Hormone Receptors & Breast Cancer Survival Abstraction Form, V. February 27, 2002
FAMILY HISTORY OF BREAST CANCER

FAMILY HISTORY OF BREAST CANCER	
Is there a family history of breast cancer?	1= Yes, there is a noted family history
(BRCA)	2= No, there is a noted negative family history of BRCA
	8 = record shows "Ø"
·	9=Undetermined, not documented
	onaccommod, not accumented

N.	1	Δ	T.	ÆΝ	/T	വ	CR	Δ	\mathbf{PHY}	HI	ST	n	RY	V
ľV	П.	м	л.	'A IV	7.	v	CTIV.	м		411	\mathbf{o}	v	1	L

Mammography History If yes, complete the follo	0=No 1=Yes 9=Unknown		
Dates:	Results:	Results Key	
	Left Right		
1/// 2//		- 1= Negative	
3///		_ 2= Benign/Negative	
4///		- 3= Probably Benign	
5/// 6//		4= Suspicious	
7//		- 5= Highly Suspicious	
8/// 9/		= 8= Incomplete/Inconclusive	
10//		– 9= Unknown	
11//			
12/// 13///			
14 / / /			
15 / /			

PATIENT HISTORY OF BREAST LESIONS <u>BEFORE</u> THE INDEX BREAST CANCER

Breast Biopsy Histor	y throughout patient reco	rds
0=No 9=Unknown		Key to Results:
1=Yes If yes, comple	te table below	1. Benign Breast Disease (BBD)
Dates	Results (specify L/R)	2. Ductal Carcinoma In Situ (DCIS)
/ /		3. Lobular Carcinoma In Situ (LCIS)
		4. Both BBD and CIS/Cancer
		5. Invasive Carcinoma (specify histopathologic type)
	- 	6. Lumpectomy or Mastectomy (unilateral or bilateral)
		not further specified
/	-	7. Cosmetic Breast Reduction
//		8. Cosmetic Breast Enlargement
//		9. Other Breast Biopsy (epithelial biopsy of breast
//		skin, nipple, fat, axillary lymph nodes, etc.)
//		99. Incomplete/Inconclusive Unknown

JFCC -- Hormone Receptors & Breast Cancer Survival Abstraction Form, V. February 27, 2002 SYMPTOMS AND LEAD-UP TO THE DIAGNOSIS OF BREAST CANCER When was the first time that a suspicion of breast cancer for this index case of breast cancer was documented in medical records or indicated by a medical procedure? ___/___/ ☐ 02=No. Explicit mention of no symptoms → If no, skip to next box. ☐ 99=No comment about symptoms → Skip to next box. Patient Reported Breast L R Unk **Date Documented** Duration (mths) □ □ □ 01=Lump or mass Symptoms (Indicate <u>all</u> that apply.) \square \square 02=Pain Specify: □ □ □ 03=Nipple discharge □ □ □ 04=Visual change □ □ □ 05=Odor □ □ 88=Other, specify: □ □ □ 99=Unspecified PATHOLOGY SUMMARIES of the specimens related to the index breast cancer. If cytology, biopsy and surgical excision were involved, please complete for each procedure. **CYTOLOGY** L R Unk Results (Indicate all that apply for <u>each</u> breast.) □ □ □ 00=Insufficient sample Date of procedure: ___/__/___/ □ □ □ 01=Normal cells □ □ □ 02=Atypical cells □ □ □ 03=Abnormal cells □ □ □ 04=Malignant cells, specify type □ □ 88=Other, specify:_ Photocopy report masking patient identifiers □ □ □ 99=Undetermined □ □ □ 00=Insufficient sample (Indicate all that apply for each breast.) □ □ □ 01=Normal cells Date of procedure: ___/__/____ □ □ □ 02=Atypical cells □ □ □ 03=Abnormal cells □ □ □ 04=Malignant cells, specify type □ □ 88=Other, specify: Photocopy report masking patient identifiers ☐ ☐ ☐ 99=Undetermined □ □ □ 00=Insufficient sample (Indicate all that apply for each breast.) Date of procedure: ___/__/___/ □ □ □ 01=Normal cells

Photocopy report masking patient identifiers

□ □ □ 02=Atypical cells
 □ □ 03=Abnormal cells
 □ □ 04=Malignant cells, specify type

□ □ □ 99=Undetermined

□ □ 88=Other, specify:

JFCC -- Hormone Receptors & Breast Cancer Survival Abstraction Form, V. February 27, 2002 Continued, PATHOLOGY SUMMARY of the specimens related to the index breast cancer.

• If cytology, biopsy & surgical excision were involved complete for each procedure.

ir cytology, bropsy & surgicul chelsion were inverse	
HISTOPATHOLOGY FROM BIOPSY	L R Unk Results
(Indicate <u>all</u> that apply for <u>each</u> breast.)	☐ ☐ 01= Atypical hyperplasia
	☐ ☐ 02= Ductal hyperplasia
Date of procedure: / / /	□ □ 03= Fibroadenoma
	☐ ☐ ☐ 04= Intraductal carcinoma in situ (DCIS)
•	☐ ☐ 05= Lobular carcinoma in situ (CIS)
	□ □ □ 06= CIS not otherwise specified
	☐ ☐ 07= Invasive ductal carcinoma (DC)
	□ □ 08= Invasive DC with DCIS
·	☐ ☐ ☐ 09= Invasive lobular carcinoma
	☐ ☐ 10= Mucinous carcinoma
	☐ ☐ ☐ 11= Medullary carcinoma
	☐ ☐ 12= Papillary carcinoma
	☐ ☐ 13= Tubular carcinoma
	☐ ☐ 14= Adenoid cystic carcinoma
Photocopy report masking patient identifiers	☐ ☐ ☐ 15= Secretory (juvenile) carcinoma
	☐ ☐ 16= Apocrine carcioma
	☐ ☐ 17= Paget's disease of the nipple
	☐ ☐ 18= Invasive cancer, NOS
	☐ ☐ ☐ 19= Cystosarcoma phyllodes
	□ □ 88= Other, specify:
	99= Undetermined
	- Chucichimica
HISTOPATHOLOGY SURGICAL EXICISION	
HISTOPATHOLOGY SURGICAL EXICISION (Indicate all that apply for each breast.)	L R Unk Results
HISTOPATHOLOGY SURGICAL EXICISION (Indicate all that apply for each breast.)	L R Unk Results □ □ □ 01= Atypical hyperplasia
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results
	L R Unk Results □ □ □ 01= Atypical hyperplasia □ □ □ 02= Ductal hyperplasia
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results □ □ 01= Atypical hyperplasia □ □ 02= Ductal hyperplasia □ □ □ 03= Fibroadenoma
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results □ □ 01= Atypical hyperplasia □ □ 02= Ductal hyperplasia □ □ 03= Fibroadenoma □ □ 04= Intraductal carcinoma in situ (DCIS)
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results □ □ 01= Atypical hyperplasia □ □ 02= Ductal hyperplasia □ □ 03= Fibroadenoma □ □ 04= Intraductal carcinoma in situ (DCIS) □ □ 05= Lobular carcinoma in situ (CIS)
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results □ □ 01= Atypical hyperplasia □ □ 02= Ductal hyperplasia □ □ 03= Fibroadenoma □ □ 04= Intraductal carcinoma in situ (DCIS) □ □ 05= Lobular carcinoma in situ (CIS) □ □ 06= CIS not otherwise specified
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results □ □ 01= Atypical hyperplasia □ □ 02= Ductal hyperplasia □ □ 03= Fibroadenoma □ □ 04= Intraductal carcinoma in situ (DCIS) □ □ 05= Lobular carcinoma in situ (CIS) □ □ 06= CIS not otherwise specified □ □ 07= Invasive ductal carcinoma (DC)
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results □ □ 01= Atypical hyperplasia □ □ 02= Ductal hyperplasia □ □ 03= Fibroadenoma □ □ 04= Intraductal carcinoma in situ (DCIS) □ □ 05= Lobular carcinoma in situ (CIS) □ □ 06= CIS not otherwise specified □ □ 07= Invasive ductal carcinoma (DC) □ □ 08= Invasive DC with DCIS
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results Ol= Atypical hyperplasia Ol= Ductal hyperplasia Ol= Ductal hyperplasia Ol= Ductal hyperplasia Ol= Ductal hyperplasia Ol= Ol= Ductal hyperplasia Ol= Ol= Intraductal carcinoma in situ (DCIS) Ol= Ol= Lobular carcinoma in situ (CIS) Ol= Ol= CIS not otherwise specified Ol= Ol= Invasive ductal carcinoma (DC) Ol= Ol= Invasive DC with DCIS Ol= Ol= Invasive lobular carcinoma
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results □ □ 01= Atypical hyperplasia □ □ 02= Ductal hyperplasia □ □ 03= Fibroadenoma □ □ 04= Intraductal carcinoma in situ (DCIS) □ □ 05= Lobular carcinoma in situ (CIS) □ □ 06= CIS not otherwise specified □ □ 07= Invasive ductal carcinoma (DC) □ □ 08= Invasive DC with DCIS □ □ 09= Invasive lobular carcinoma □ □ 01= Mucinous carcinoma
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results O 1= Atypical hyperplasia O 2= Ductal hyperplasia O 3= Fibroadenoma O 4= Intraductal carcinoma in situ (DCIS) O 5= Lobular carcinoma in situ (CIS) O 6= CIS not otherwise specified O 7= Invasive ductal carcinoma (DC) O 8= Invasive DC with DCIS O 9= Invasive lobular carcinoma O 10= Mucinous carcinoma O 11= Medullary carcinoma
(Indicate <u>all</u> that apply for <u>each</u> breast.) Date of procedure:///	L R Unk Results Ol= Atypical hyperplasia Ol= Ol= Atypical hyperplasia Ol= Ductal hyperplasia Ol= Ductal hyperplasia Ol= Ol= Fibroadenoma Ol= Ol= Intraductal carcinoma in situ (DCIS) Ol= Ol= CIS not otherwise specified Ol= Ol= Ol= Invasive ductal carcinoma (DC) Ol= Ol= Invasive DC with DCIS Ol= Ol= Invasive lobular carcinoma Ol= Ol= Mucinous carcinoma Ol= Ol= Mucinous carcinoma Ol= Ol= Medullary carcinoma Ol= Ol= Papillary carcinoma
(Indicate <u>all</u> that apply for <u>each</u> breast.)	L R Unk Results O 1= Atypical hyperplasia O 2= Ductal hyperplasia O 3= Fibroadenoma O 4= Intraductal carcinoma in situ (DCIS) O 5= Lobular carcinoma in situ (CIS) O 6= CIS not otherwise specified O 7= Invasive ductal carcinoma (DC) O 8= Invasive DC with DCIS O 9= Invasive lobular carcinoma O 0 10= Mucinous carcinoma O 11= Medullary carcinoma O 12= Papillary carcinoma O 13= Tubular carcinoma
(Indicate <u>all</u> that apply for <u>each</u> breast.) Date of procedure:///	L R Unk Results □ □ 01= Atypical hyperplasia □ □ 02= Ductal hyperplasia □ □ 03= Fibroadenoma □ □ 04= Intraductal carcinoma in situ (DCIS) □ □ 05= Lobular carcinoma in situ (CIS) □ □ 06= CIS not otherwise specified □ □ 07= Invasive ductal carcinoma (DC) □ □ 08= Invasive DC with DCIS □ □ 09= Invasive lobular carcinoma □ □ 09= Invasive lobular carcinoma □ □ 11= Medullary carcinoma □ □ 11= Medullary carcinoma □ □ 12= Papillary carcinoma □ □ 13= Tubular carcinoma □ □ 14= Adenoid cystic carcinoma
(Indicate <u>all</u> that apply for <u>each</u> breast.) Date of procedure:///	L R Unk Results □ □ 01= Atypical hyperplasia □ □ 02= Ductal hyperplasia □ □ 03= Fibroadenoma □ □ 04= Intraductal carcinoma in situ (DCIS) □ □ 05= Lobular carcinoma in situ (CIS) □ □ 06= CIS not otherwise specified □ □ 07= Invasive ductal carcinoma (DC) □ □ 08= Invasive DC with DCIS □ □ 09= Invasive lobular carcinoma □ □ 10= Mucinous carcinoma □ □ 11= Medullary carcinoma □ □ 12= Papillary carcinoma □ □ 13= Tubular carcinoma □ □ 14= Adenoid cystic carcinoma □ □ 15= Secretory (juvenile) carcinoma □ □ 16= Apocrine carcioma □ □ 17= Paget's disease of the nipple
(Indicate <u>all</u> that apply for <u>each</u> breast.) Date of procedure:///	L R Unk Results O 1= Atypical hyperplasia O 2= Ductal hyperplasia O 3= Fibroadenoma O 4= Intraductal carcinoma in situ (DCIS) O 5= Lobular carcinoma in situ (CIS) O 6= CIS not otherwise specified O 7= Invasive ductal carcinoma (DC) O 8= Invasive DC with DCIS O 9= Invasive lobular carcinoma O 09= Invasive lobular carcinoma O 10= Mucinous carcinoma O 11= Medullary carcinoma O 12= Papillary carcinoma O 13= Tubular carcinoma O 14= Adenoid cystic carcinoma O 15= Secretory (juvenile) carcinoma O 16= Apocrine carcioma
(Indicate <u>all</u> that apply for <u>each</u> breast.) Date of procedure:///	L R Unk Results □ □ 01= Atypical hyperplasia □ □ 02= Ductal hyperplasia □ □ 03= Fibroadenoma □ □ 04= Intraductal carcinoma in situ (DCIS) □ □ 05= Lobular carcinoma in situ (CIS) □ □ 06= CIS not otherwise specified □ □ 07= Invasive ductal carcinoma (DC) □ □ 08= Invasive DC with DCIS □ □ 09= Invasive lobular carcinoma □ □ 10= Mucinous carcinoma □ □ 11= Medullary carcinoma □ □ 12= Papillary carcinoma □ □ 13= Tubular carcinoma □ □ 14= Adenoid cystic carcinoma □ □ 15= Secretory (juvenile) carcinoma □ □ 16= Apocrine carcioma □ □ 17= Paget's disease of the nipple
(Indicate <u>all</u> that apply for <u>each</u> breast.) Date of procedure:///	L R Unk Results O 1= Atypical hyperplasia O 2= Ductal hyperplasia O 3= Fibroadenoma O 4= Intraductal carcinoma in situ (DCIS) O 5= Lobular carcinoma in situ (CIS) O 6= CIS not otherwise specified O 7= Invasive ductal carcinoma (DC) O 8= Invasive DC with DCIS O 9= Invasive lobular carcinoma O 9= Invasive lobular carcinoma O 10= Mucinous carcinoma O 12= Papillary carcinoma O 12= Papillary carcinoma O 13= Tubular carcinoma O 15= Secretory (juvenile) carcinoma O 16= Apocrine carcioma O 17= Paget's disease of the nipple O 18= Invasive cancer, NOS

JFCC -- Hormone Receptors & Breast Cancer Survival Abstraction Form, V. February 27, 2002 STAGING (Please flag any conflicting pathology, staging, treatment or follow-up data, & discuss with investigators)

	PLEASE PHOTOCOPY PATHOLOGISTS REPORTS minus patient identifiers
Primary Tumor	TX Primary tumor cannot be assessed
(T)	☐ TO No evidence of primary tumor
•	☐ Tis Carcinoma in situ
	☐ T1 Tumor ≤2 cm in greatest dimension
	pT1mic Microinvasion 0.1 cm or less in greatest dimension
	☐ T1a Tumor >0.1 to ≤0.5 cm in greatest dimension
	☐ T1b >0.5 to ≤1 cm in greatest dimension
	☐ T1c >1cm to ≤2 cm in greatest dimension
	T2 Tumor >2 cm to 5 cm
	☐ T3 Tumor >5 cm
	☐ T4 Tumor of any size with direct extension to chest wall or skin
	☐ T4a Extension to chest wall
	☐ T4b Edema or ulceration of the skin or satellite skin nodules confined to same breast
	T4c Both T4a and T4b
	☐ T4d Inflammatory carcinoma
	Paget's disease associated with a tumor is classified by size of the tumor
	Multifocal
Regional Lymph Nodes	NX Regional LN cannot be assessed (e.g., previously removed or were not sampled)
(N)	No regional LN metastasis
	☐ N1 Spread to movable ipsilateral axillary LN(s)
	N2 Spread to ipsilateral axillary LN(s) fixed to one another or to other structures
	☐ N3 Spread to ipsilateral internal mammary LN(s)
Dath alogic Classification	Taxiy badaa 11 Na aaraa 1
Pathologic Classification	pNX Regional LNs cannot be assessed
(pN)	pNO No regional LN metastasis
# T NI o a siting	pN1 Metastasis to movable ipsilateral axillary LN(s)
# LN positive	□ pN1a Only micrometastasis (none larger than 0.2 cm) □ pN1hi Motostogis in 1 to 3 I No. > 0.2 to <2 cm in greatest dimension
H T NI Accas J	pN1bi Metastasis in 1 to 3 LNs, >0.2 to <2cm in greatest dimension
# LN tested	pN1bii Metastasis to 4 or more LNs, >0.2 to <2cm in greatest dimension
	 □ pN1biii Extension of tumor beyond capsule of a LN <2 cm in greatest dimension □ pN1biv Metastasis to LN ≥2 cm in dimension
	pN2 Metastasis to insilateral axillary LNs that are fixed to other LN(s) or structures
	pN3 Metastasis to ipsilateral internal mammary LN(s)
Distant Metastasis	☐ MX ☐ M0 ☐ M1 (includes metastasis to ipsilateral supraclavicular LN(s)
	If M=1, what are the number of metastatic organ sites?
PARAMONE THE PARAM	Specify sites (which organs)
What was the TNM stage gro	oup, if O (TIS) O I O II O IIA O IIB O III O IIIA O IIIB O IV
provided?	☐ Stage X (cannot be determined) ☐ Not provided
Histopathologic	X= cannot be assessed \square G1= well differentiated \square G2= moderately differentiated,
☐ G:	B= poorly differentiated G4= Undifferentiated G9 = Unknown

JFCC -- Hormone Receptors & Breast Cancer Survival Abstraction Form, V. February 27, 2002
TREATMENT

treatment? 2 = treatment primarily carried out elsewhere 3 = treatment advised 4 = treatment advised 5 = no treatment advised 6 = no treatment given, reasons unknown 9 = unknown whether treatment received Was the breast cancer treated with SURGERY? 0 = no 1 = yes 9 = unknown 1 = breast conserving surgery (lumpectomy, wide excision, partial mastectomy, segmental mastectomy or quadrantectomy) 2 = total mastectomy without axillarly lymph node dissection 3 = modified radical mastectomy (simple mastectomy + lymph node dissection) 4 = radical mastectomy (includes pectoral muscle dissection) 5 = lumpectomy + ly- node removal Was the breast cancer treated with RADIATION? Was the breast cancer treated with CHEMOTHERAPY? (other than tamoxifen) 0 = no 1 = yes 9 = unknown If yes, what was the start date? / / What were the agents? Was the breast cancer treated with HORMONE OR ENDOCRINE THERAPY other than tamoxifen? Was the breast cancer treated with HORMONE OR ENDOCRINE THERAPY other than tamoxifen? If yes, which of the following apply? (If no mention is made assume the default of "0") Ovarian ablation by surgery No = 0 Yes = 1 Ovarian ablation by radiation No = 0 Yes = 1 Progestins (eg. megesterol acetate or medroxyprogesterone acetate) No = 0 Yes = 1 Estrogens No = 0 Yes = 1 Adrenalectomy No = 0 Yes = 1 Adrenalectomy No = 0 Yes = 1	Did the patient receive 1 = treatment carried out (mostly at HFHS)					
## Treatment advised 5 = no treatment given, reasons unknown 9 = unknown whether treatment received Was the breast cancer treated with SURGERY? 0 = no 1 = yes 9 = unknown Breast cancer treated with SURGERY? 1 = breast conserving surgery (lumpectomy, wide excision, partial mastectomy, segmental mastectomy or quadrantectomy) 2 = total mastectomy without axillary lymph node dissection 3 = modified radical mastectomy (simple mastectomy + lymph node dissection) 4 = radical mastectomy (includes pectoral muscle dissection) 5 = lumpectomy +/- node removal Was the breast cancer treated with RADIATION? Was the breast cancer treated with GHEMOTHERAPY? (other than tamoxifen) 0 = no 1 = yes 9 = unknown Was the breast cancer treated with HORMONE OR ENDOCRINE THERAPY other than tamoxifen? Was the breast cancer treated with HORMONE OR ENDOCRINE THERAPY other than tamoxifen? Was the breast cancer treated with HORMONE OR ENDOCRINE THERAPY other than tamoxifen? Was the breast cancer treated with HORMONE OR ENDOCRINE THERAPY other than tamoxifen? Was the breast cancer treated with HORMONE OR ENDOCRINE THERAPY other than tamoxifen? Was the breast cancer treated with HORMONE OR ENDOCRINE THERAPY other than tamoxifen? O = no 1 = yes	treatment?	2 = treatment primarily carried out elsewhere				
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	Adrenalectomy No = 0	Yes = 1				
Hypophysectomy $No = 0$ $Yes = 1$	Hypophysectomy No =	0 Yes = 1				

JFCC -- Hormone Receptors & Breast Cancer Survival Abstraction Form, V. February 27, 2002 RESPONSE and FOLLOW-UP

TEDDI OTIDE UIIGI OZZOVI OZ								
Did cancer recur or spread (local or distant pro	_		-		own			
If yes, When was it 1 st noted?//		_ To	where?		1 6	1 1	0 16	
What was the diagnosis of recurrence/progress	ion based	on 1=pa	athology	2=clinic	al 3	=both	9=not stated	<u> </u>
Did the patient develop one or more subsequen								
0=no 1=yes 9= unknown If yes, Histopatl	_				'	<u> </u> — — ′, -		
0=no 1=yes 9= unknown If yes, Histopati		7		Date?	/			
Did the patient develop other types of primary				D-4-0		, ,		
0=no 1=yes 9= unknown If yes, type of c						',',-		
0=no 1=yes 9= unknown If yes, type of c		:C:4	:- 2nd	Date?				
Did the patient develop another type of cancer,								
0=no 1=yes 9= unknown If yes, type of c				_ Date? _ Date?	'	',— <i>—</i>		
0=no 1=yes 9= unknown If yes, type of conditions Do the records indicate that the patients died?		rec If a	ec who		leath	date?	/ /	
If patient died, were causes of death described		-		causes of				
0 = no 1 = yes	i ii ye.	s, what	were the	causes of	. ucai	.11 :		
0 - no 1 - yes				****				
If the patient was alive at last contact, what was	s the date	of the 1	ast cont	act?	1	1		
if the patient was anve at last contact, what was	is the date	or the r	asi com	act:				
ALCOHOL USE (documented 5 years b	efore to	3 year	s after	diagnosi	s)			
Regarding ALCOHOL consumption the rec	cords indi	cate th	e follov	ving:				
0 = Abstained from alcohol / No consumption (Date		Date		Date	Date	
1 = Mild use (past or present) (1-13 drinks/mo								
2 = Moderate use (past or present) (4-14 drinks								
3 = Past heavy use (>14 drinks/wk)								
4 = Current heavy use (>14 drinks/wk) Code # Code # Code # Code #					#			
5 = Heavy use, not otherwise specified (>14 drinks/wk)								
7 = Alcohol was consumed by not quantified							Ì	
8 = record shows "Ø"								
9 = No alcohol data were available								
Drinks/time is a guideline. Drink ~ 1 bottle beer ~ 1 glass wine ~ 1 shot of liquor								
MARIJUANA/CANNIBIS USE (docum	antad 5 x	zaare h	afara t	a 3 waare	ofte	r diaan	vocie)	
Regarding MARIJUANA/CANNIBIS use						ulagii	10313)	
0 = Non-user	Date	us muic	Date	TOHOWIN	Dat		Date	
0 = Non-user 1 = Past regular use	Date		Date		Dai		Date	
2 = Current regular use								
3 = Both past and current use	Code # Code # Code #							
8 = record shows "Ø"	Code # Code # Code		Code #					
= record shows "Ø" = No data were available								
7 140 data word available								
ILLICIT DRUG USE (documented 5 ye	ears befor	re to 3	years a	ıfter diag	nosi	is)		
(e.g., cocaine, crack, heroin, or non-spec			-	_		•	٠	
Regarding ILLICIT DRUG use the record								
0 = Non-user	Date		Date		Dat	e	Date	
1 = Past regular use								
2 = Current regular use	Type of o	Inio	Type o	of drug	Tvr	e of drug	g Type of	drug
3 = Both past and current use	-, pc 0, \	<u>-</u> 5	- , po c	 5	- 11	urug		
8 = record shows "Ø"	Code #		Code #		Coc	le #	Code #	
	Couc #		Couc #	т	COC	ιcπ	Coue #	
9 = No data were available	Ì						İ	

SMOKING HISTORY

Cigarette smoking data were available in the records (documented 5 years before to 3 years after diagnosis) 0=no 1=yes?

If yes, complete for each recording of smoking history that occurs on a different day or in a different record, even if the data appear redundant. If smoking data were not available for the specified time period, then use available smoking data from any time period.

DATE	"Ø" smoking	SMOKER 0=Never 1=Ever	SMOKER 0=Never Smoker 2=Past Smoker 3=Current Smoker	QUIT HOW LONG AGO? (in years, use decimals if needed)	INTENSITY cigarettes/ day	C. INTENSITY packs/day	D. DURATION # of years smoked	CxD= PACK-YEARS SMOKED
				•				

JFCC -- Hormone Receptors & Breast Cancer Survival Abstraction Form, V.February 27, 2002 Please list all medications taken by the patient for 3 years prior to the breast cancer diagnosis.

Medication	Indication why it was given	Estimate Usage 1 = Short term (< 6 months) 2 = Long term (≥ 6 months) 9 = unknown
TIONAL INFORMATI		
If the chart information wa Comments:	as incomplete or insufficient, check box an	nd specify below.
What is the date on the fire	st record for this patient (not limited to the	ne abstraction period)? /
	gnosis, for how many years/months were r	- ,
	years had a gap > 2 year, was it because the	
		ircle 1 if appropriate)
Was being seen else	·	** *
	•	
Don't know the rea	1 – yes	
	t record for this patient (not limited to the	e abstraction period)?

JFCC -- Hormone Receptors & Breast Cancer Survival Abstraction Form, V.February 27, 2002 COMORBIDITIES

Please document all of the comorbidities (Circle and indicate Yes "= 1") that the patient had a history of in their records from 3 years prior to diagnosis to 6 months following diagnosis or until the first treatment, which ever comes first, regardless of when the comorbidities actually occurred. The comorbidity did not have to have been present during this period, it just needed to be documented in the medical records during this time period. If any information is given as to when the comorbidity or sign/symptom was diagnosed or occurred and its duration, please write it down beside its listing on the abstraction form.

For diagnosis/occurrence, please specify the year or date.

For duration, please specify the number of years/months.

The systems are listed in the following order:

- (1) INFECTIOUS AND PARASITIC DISEASES
- (2) PREVIOUS NEOPLASMS
- (3) ENDOCRINE, NUTRITIONAL/METABOLIC DISEASES, & IMMUNITY DISORDERS
- (4) DISEASES OF THE BLOOD AND BLOOD-FORMING ORGANS
- (5) MENTAL DISORDERS
- (6) DISEASES OF THE NERVOUS SYSTEM & SENSE ORGANS
- (7) DISEASES OF THE CIRCULATORY SYSTEM
- (8) DISEASES OF THE RESPIRATORY SYSTEM
- (9) DISEASES OF THE DIGESTIVE SYSTEM
- (10) DISEASES OF THE GENITOURINARY SYSTEM
- (11) COMPLICATIONS OF PREGNANCY, CHILDBIRTH, AND THE PUERPERIUM
- (12) DISEASES OF THE SKIN AND SUBCUTANEOUS TISSUE
- (13) DISEASES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE
- (14) CONGENITAL ANOMALIES
- (15) CERTAIN CONDITIONS ORIGINATING IN THE PERINATAL PERIOD
- (16) INJURY / TRAUMA & POISONING
- (17) SYMPTOMS & SIGNS of the index cancer, & ILL-DEFINED CONDITIONS

(1) INFECTIOUS AND PARASITIC DISEASES (ICD 001-139) No = 0 the default, YES = 1 Tuberculosis Is this a recent infection (< 3 years old) or an active infection under treatment? Yes / No

CM1 Tuberculosis Is this a recoCM2 Septicemia (except in labor)

CM3 Bacterial infection, unspecified site

CM4 Mycoses

CM5 HIV infection / AIDS

CM6 Hepatitis (infectious, not primarily alcohol-related, see #150) Circle: Hepatitis virus A, B, C, D, E, G, or other.

CM7 Viral infection (not hepatitis)

CM8 Other infections, including parasitic

CM9 Sexually transmitted infections = STD (not HIV or hepatitis)

CM10 (Immunizations and screening for infectious disease, If yes, specify

CM248 Gangrene

(2) PREVIOUS NEOPLASMS (ICD 140-239)

Cancer (CA) of	A. Present	B. Metastasis	C.	D.	E. Yr of
	No=0, Yes=1	No=0, Yes=1	Stage	Histology	diagnosis
CM11 Head & neck					
CM12 Esophagus					٠
CM13 Stomach					
CM14 Colon					
CM15 Rectum & anus					
CM16 Liver & intrahepatic bile duct					
CM17 Pancreas					
CM18 Other gastrointestinal organs, peritoneum					
CM19 Bronchus, lung					
CM20 Other respiratory & intra-thoracic					
CM21 Bone & connective tissue					
CM22 Melanomas of skin			,		
CM23 Other non-epithelial cancer of skin					
CM24 Breast					
CM25 Uterus		·			
CM26 Cervix	,				
CM27 Ovary					
CM28 Other female genital organs					
CM29 Prostate					
CM30 Testis	-				
CM31 Other male genital organs					
CM32 Bladder					
CM33 Kidney and renal pelvis					
CM34 Other urinary organs					
CM35 Brain and nervous system					
CM36 Thyroid					
CM37 Hodgkin's disease					
CM38 Non-Hodgkin's lymphoma					
CM39 Leukemias					
CM40 Multiple myeloma					
CM41 Other and unspecified primary			<u> </u>		
CM42 Secondary malignancies					
CM43 Malignant neoplasm, unspecified site				· · · · · · · · · · · · · · · · · · ·	
CM44 CA, unspecified/uncertain nature or behavior					7
CM45 Maintenance chemotherapy, radiotherapy		N/A	N/A	N/A	N/A
CM46 Benign neoplasm of uterus, i.e., fibroids	-	N/A	N/A	IVA	14/17
(leiomyoma; myoma; fibromyoma)	-	I III	14/7		
CM47 Other and unspecified benign neoplasm		N/A	N/A		

(2) THE CONTRACT	IMPITTION AT MERITANDA TO DIGITA ONG	O THOUSEN DECORDED (IOD 040 050)			
(3) ENDOCRINE, NUTRITIONAL/METABOLIC DISEASES, & IMMUNITY DISORDERS (ICD 240-279)					
CM48 Thyroid disorders e.g., goiter, hyperthyroidism, hypothyroidism, thyroiditis. If yes, specify CM49 Diabetes mellitus without complication. If yes, is it insulin-dependent? Yes / No					
	complications. If yes, specify, e.g., ketoacide				
	ophthalmic, neurologic, circulatory, or other/unspecified complications.				
If yes, is it insulin-dependent? Yes / No					
CM51 Other endocrine disorders, e.g., parathyroid, pituitary and its hypothalamic control, adrenal or polyglandular					
disorders, premature ovarian failure (menopause <40years). If yes, specify					
CM301 Obesity / hyperalimentation documented by physician/clinician/nurse in medical records CM52 Nutritional deficiencies (specific). If yes, specify					
CMS2 Nutritional deficiencies (specific). If yes, specify CMS2B Under-nutrition/malnutrition (general/unspecified)					
CM53 Disorders of lipid metabolism, e.g., hypercholesterolemia, hyperlipidemia. If yes, specify					
CM54 Gout and other crystal arthropathies, If yes, which of the following apply?					
	mild or not further specified				
	with nephropathy				
	with other specific manifestations	1			
CM54E Other	crystal arthropathy	•			
	metabolic disorders, If yes, please specify of				
Water balance	CM55B Dehydration	CM55C Over-hydration			
Extracellular fluid volume	CM55D Contraction	CM55E Expansion / Overload			
Sodium (Na)	CM55F Hyponatremia	CM55G Hypernatremia			
Potassium (K)	CM55H Hypokalemia (hypopotassemia)	CM55I Hyperkalemia (hyperpotassemia)			
Calcium (Ca)	Calcium (Ca) CM55J Hypocalcemia CM55K Hypercalcemia				
Phosphate (P) CM55L Hypophosphatemia CM55M Hyperphosphatemia					
Magnesium (Mg) CM55N Hypomagnesemia CM55O Hypermagnesemia					
Acid-Base Metabolism					
	CM55R Respiratory Acidosis CM55S Respiratory Alkalosis				
Others, specify	Others, specify CM55T .				
molybdenum, & copper CM56 Cystic fibrosis	netabolism, including iron, iodine, fluorine, z. r. If yes, specify				
CM253 Allergic reactions CM303 Amyloidosis					
CM58 Other nutritional, endocrine, and metabolic disorders, If yes, specify					
	, ,				
(4) DISEASES OF T	THE BLOOD AND BLOOD-FORMING	G ORGANS (ICD 280-289)			
		, , , , , , , , , , , , , , , , , , , ,			
	· ·				
CM63 Diseases of white bloo		·			
Civio+ Other hematologic con	CM64 Other hematologic conditions, including spleen disorders				
	RDERS (ICD 290-319)				
CM65 Mental retardation		•			
	al disorders, including acute intoxication, dep	•			
		unine, hallucinogen, opioid, cocaine or other or			
	e or abuse. Specify which drugs were used _				
CM68 Senility and organic n	nental disorders, including senile and arterios	clerotic dementia, Alzheimer's disease.			
	cluding depressive disorder, bipolar affective	disorder, manic-depressive psychosis.			
CM70 Schizophrenia and rel	ated disorders				
CM71 Other psychoses					
CM72 Anxiety, somatoform,	dissociative, and personality disorders				

CM75 Personal history of mental disorder, mental & behavioral problems, observation/screening for mental condition

CM73 Preadult disorders CM74 Other mental conditions

(6) DISEASES OF THE NERVOUS SYSTEM & SENSE ORGANS (ICD 320-389)

CENT	RAL NERVOUS SYSTEM
CM76	Meningitis (except that caused by tuberculosis or sexually transmitted disease)
CM77	Encephalitis (except that caused by tuberculosis or sexually transmitted disease)
CM78	Other CNS infection and poliomyelitis If yes, specify
CM79	Parkinson's disease
CM80	Multiple sclerosis
CM81	Other hereditary & degenerative nervous system conditions, e.g., ALS. If yes, specify
CM82	Paralysis (except that secondary to cerebrovascular diseases which goes under # 113)
CM83	Epilepsy, convulsions
CM84	Headache, including migraine
CM85	Coma, stupor, and brain damage
EYE	
CM86	Cataract
CM87	Retinal detachments, defects, vascular occlusion, and retinopathy
CM88	Glaucoma
	Blindness and vision defects
	Inflammation, infection of eye (except that caused by tuberculosis or sexually transmitted disease)
CM337	Near-sightedness (myopia), far-sightedness (hyperopia), astigmatism or needing reading glasses (presbyopia)
CM91	Other eye disorders If yes, specify
AUDI.	TORY SYSTEM & OTHERS
CM92	Otitis media and related conditions
CM93	
CM94	Other ear and sense organ disorders If yes, specify
CM95	Other nervous system disorders If yes, specify
	(7) DISEASES OF THE CIRCULATORY SYSTEM (ICD 390-459)
CM96	Heart valve disorders ,
	Peri-, endo-, and myocarditis, cardiomyopathy (except that caused by tuberculosis or STD)
	Essential hypertension
	Hypertension with complications and secondary hypertension If yes, specify
CM100	Myocardial infarction How long ago was most recent MI?
CM101	Coronary atherosclerosis and other heart disease
	Angina (non-specific or non-angina chest pain is coded under #322)
	Pulmonary heart disease (cor pulmonale)
	Other or ill-defined heart disease
	Conduction disorders
	Cardiac dysrhythmias / arrhythmias
	Cardiac arrest or ventricular fibrillation
	Congestive heart failure
	Acute cerebrovascular disease
	Occlusion or stenosis of precerebral arteries
	Other and ill-defined cerebrovascular disease
	Transient cerebral ischemia
	Late effects of cerebrovascular disease, i.e., plegia or hemiplegia
	Peripheral and visceral atherosclerosis
CM115	Aortic, peripheral, & visceral artery aneurysms,
	CM115B If yes, where was it located?
	CM115C What was its size? cm.
	CM115D Was it surgically corrected? No = 0, Yes = 1.
CM116	
	Other circulatory disease, including hypotension
	Phlebitis, thrombophlebitis and thromboembolism
	Varicose veins of lower extremity
	Hemorrhoids
CM121	Other diseases of veins and lymphatics

•	(0) DICE A CEC OF THE DECDID A TODY CYCTEM (ICD 400 510)
G7.5400	(8) DISEASES OF THE RESPIRATORY SYSTEM (ICD 460-519)
	Pneumonia (except that caused by tuberculosis or sexually transmitted disease)
	Influenza
	Acute and chronic tonsillitis
CM125	Acute bronchitis
CM126	Other upper respiratory infections, If yes, specify
CM127	Chronic obstructive pulmonary disease & bronchiectasis, If yes, specify:
	CM127B COPD otherwise not specified
	CM127C Emphysema
	CM127D Chronic bronchitis
	CM127E Bronchiectasis
CM129	Asthma
	Pulmonary fibrosis / interstitial lung diseases
	Aspiration pneumonitis, food/vomitus
	Pleurisy, pneumothorax, pulmonary collapse (atelectasis)
	Respiratory failure, insufficiency, arrest (adult)
CM132	Lung disease due to external agents, including pneumoconioses, e.g., anthracosis, silicosis, asbestosis, berylliosis,
•	siderosis, stannosis, & baritosis.
	Other lower respiratory disease
CM134	Other upper respiratory disease
	(9) DISEASES OF THE DIGESTIVE SYSTEM (ICD 520-579)
CM135	Intestinal infection
CM136	Disorders of teeth and jaw
	Diseases of mouth, excluding dental
	Esophageal disorders
	Gastroduodenal ulcer (except hemorrhage)
	Gastritis and duodenitis
	Other disorders of stomach and duodenum
	Appendicitis and other appendiceal conditions
	Abdominal hernia, If yes, was it accompanied by obstruction or gangrene? No = 0, Yes = 1.
	Regional enteritis and ulcerative colitis, including inflammatory bowel diseases, such as Crohn's disease &
	ulcerative colitis.
	Intestinal obstruction without hernia, e.g., paralytic ileus, impaction, adhesions. If yes, specify
	Diverticulosis and diverticulitis
_	Anal and rectal conditions
	Peritonitis and intestinal abscess
	Biliary tract disease, e.g., cholecystitis, cholelithiasisis
	Liver disease, alcohol-related
	Other liver diseases, e.g., liver disease or cirrhosis without mention of alcohol, liver abscess, ascites.
CM152	Pancreatic disorders (not diabetes)
	Gastrointestinal hemorrhage If yes, specify
	Noninfectious gastroenteritis
CM155	Other gastrointestinal disorders, e.g., constipation, dysphagia. If yes, specify
	(10) DISEASES OF THE GENITOURINARY SYSTEM (580-629)
CM156	Nephritis, nephrosis, renal sclerosis, If yes, specify
CM157	Acute and unspecified renal failure
	Chronic renal failure
CM150	Has the patient had dialysis? If yes, earliest date and last date Urinary tract infections, If yes, specify if of kidney or cystitis/urethritis:
CMITTON	Colorlar of win our treat (well-this is) If yes, specify if of Cliffy and the color of the color
CM1160	Calculus of urinary tract (urolithiasis) If yes, specify if of kidney or ureter or bladder:
	is the composition?: calcium oxalate; uric acid; cystine; struvite = magnesium ammonium phosphate, other, unknown
	Other diseases of kidney and ureters, e.g., hydronephrosis
	Other diseases of bladder and urethra
	Genitourinary symptoms and ill-defined conditions, e.g., hematuria, dysuria, retention of urine.
	ASES OF THE MALE GENITAL ORGANS
	Hyperplasia of prostate
CM165	Inflammatory conditions of male genital organs, If yes, specify
	Other male genital disorders, If yes, specify

DISEASES OF THE FEMALE GENITAL ORGANS CM167 Nonmalignant breast conditions CM168 Inflammatory diseases of female pelvic organs, e.g., pelvic peritoneal adhesions, cervicitis / endocervicitis, pelvic inflammatory disease (including endometritis, salpingitis and ooporitis). If yes, specify CM169 Endometriosis CM170 Prolapse of female genital organs CM171 Menstrual disorders CM172 Ovarian cyst CM173 Menopausal disorders CM174 Female infertility CM175 Other female genital disorders (11) COMPLICATIONS OF PREGNANCY, CHILDBIRTH, AND THE PUERPERIUM (IDC 630-677) CM176 Contraceptive and procreative management CM177 Spontaneous abortion CM178 Induced abortion CM179 Post-abortion complications CM180 Ectopic pregnancy CM181 Other complications of pregnancy, e.g., genitourinary infection during pregnancy, anemia during pregnancy, mental disorder during pregnancy, missed abortion, hyperemesis gravidarum, infectious/parasitic complications in mother affecting pregnancy. If yes, specify CM182 Hemorrhage during pregnancy, abruptio placenta, placenta previa CM183 Hypertension complicating pregnancy, childbirth and the puerperium, e.g., preeclampsian/eclampsia. CM184 Early or threatened labor CM185 Prolonged pregnancy CM186 Diabetes or abnormal glucose tolerance complicating pregnancy, childbirth, or the puerperium CM187 Malposition, malpresentation CM188 Fetopelvic disproportion, obstruction CM189 Previous cesarean section CM190 Fetal distress and abnormal forces of labor, e.g., fetal distress, uterine inertia, precipitate labor. CM191 Polyhydramnios & other problems of amniotic cavity, e.g., premature rupture of membranes, infection of amnion. CM192 Umbilical cord complication CM193 Trauma to perineum and vulva CM194 Forceps delivery CM195 Other complications of birth, puerperium affecting management of mother, e.g., postpartum hemorrhage, cervical incompetence, rhesus isoimmunization, interuterine death, failed induction. CM196 Normal pregnancy and/or delivery (12) DISEASES OF THE SKIN AND SUBCUTANEOUS TISSUE (ICD 680-709) CM197 Skin and subcutaneous tissue infections, e.g., cellulitis or abscess. CM198 Other inflammatory condition of skin CM199 Chronic ulcer of skin CM200 Other skin disorders (13) DISEASES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE (ICD 710-739) CM201 Infective arthritis and osteomyelitis (except that caused by tuberculosis or sexually transmitted disease) CM202 Rheumatoid arthritis and related disease CM203 Osteoarthritis CM204 Other non-traumatic joint disorders (place gout and other crystalline metabolic arthropathic disorders in #54) CM205 Spondylosis, intervertebral disc disorders, other back problems CM206 Osteoporosis CM206B Osteopenia CM207 Pathological fracture CM208 Acquired foot deformities CM209 Other acquired deformities CM210 Systemic lupus erythematosus and connective tissue disorders CM211 Other connective tissue disease CM212 Other bone disease and musculoskeletal deformities CM305 Limb amputation, If yes, then check if #254 applies.

CM339 Hip replacement

(14) CONGENITAL ANOMALIES (ICD 740-759)

- CM213 Cardiac and circulatory congenital anomalies
- CM214 Digestive congenital anomalies
- CM215 Genitourinary congenital anomalies
- CM216 Nervous system congenital anomalies
- CM217 Other congenital anomalies

(15) CERTAIN CONDITIONS ORIGINATING IN THE PERINATAL PERIOD (ICD 760-779)

- CM218 Liveborn
- CM219 Short gestation, low birth weight, and fetal growth retardation
- CM220 Intrauterine hypoxia and birth asphyxia
- CM221 Respiratory distress syndrome
- CM222 Hemolytic jaundice and perinatal jaundice
- CM223 Birth trauma
- CM224 Other perinatal conditions

(16) INJURY / TRAUMA & POISONING (800-999)

- CM225 Joint disorders and dislocations, trauma-related
- CM226 Fracture of neck of femur (hip)
- CM227 Spinal cord injury
- CM228 Skull and face fractures
- CM229 Fracture of upper limb
- CM230 Fracture of lower limb
- CM231 Other fractures
- CM232 Sprains and strains
- CM233 Intracranial injury
- CM234 Crushing injury or internal injury
- CM235 Open wounds of head, neck, and trunk
- CM236 Open wounds of extremities
- CM237 Complication of device, implant or graft
- CM238 Complications of surgical procedures or medical care
- CM239 Superficial injury, contusion
- CM240 Burns
- CM241 Poisoning by psychotropic agents
- CM242 Poisoning by other medications and drugs
- CM243 Poisoning by nonmedicinal substances
- CM244 Other injuries and conditions due to external causes
- CM306 Gunshot injury

(17) SYMPTOMS & SIGNS of the index cancer, & ILL-DEFINED CONDITIONS (ICD 780-799) CM307A Prior to the index cancer under study, was the patient symptomatic. No=0, Yes=1.

CM307B If symptomatic, what was the duration of symptoms? ____ months.

If symptomatic, complete the table below.

GENERAL	CNAME Company Spiriture
GENERAL	CM245 Syncope, fainting
	CM249 Shock
	CM252 Fatigue and malaise, i.e., tiredness, weakness, lethargy
	CM246 Fever, tumor-related or of unknown origin
	CM308 Chills, sweats, night sweats, diaphoresis (excess or profuse perspiration)
	CM309 Weight loss (unintentional) How many pounds were lost?, Over how many months?
	Was weight loss intentional (i.e., due to dieting)? = 0, or was it disease related? = 1
GASTRO-	CM250 Nausea, vomiting, emesis
INTESTINAL	CM310 Anorexia, loss of appetite, decreased appetite
	CM311 Hearthurn
	CM336 Jaundice, icterus
RESPIRA-	CM312 Upper respiratory symptoms, epistaxis
TORY /	CM313 Throat symptoms, e.g., dysphagia, difficulty swallowing, sore throat, swollen throat, hiccups,
CHEST	choking sensation, hoarseness (rough or harsh quality of voice), dysphonia (any impairment of voice, a
	difficulty in speaking)
	CM314 Cough
	CM315 Dyspnea, shortness of breath (SOB), excertional dyspnea, orthopnea (inability to breath except
	in an upright position)
	CM316 Wheezing (i.e., whistling noises, high pitch, made during breathing) or Stridor (a harsh sound,
	audible without a stethoscope and predominantly inspiratory, often from obstruction)
	CM317 Respiratory congestion
	CM318 Palpitations
	CM319 Hemoptysis (coughing up blood from the respiratory tract)
	CM320 Cyanosis
	CM321 Finger clubbing
PAIN	CM251 Abdominal pain
	CM322 Chest pain other than angina
	CM323 Pain of the back
	CM324 Pain of the shoulder
	CM325 Other pain, e.g., arthralgia, neuralgia, pain in extremities.
NODES,	CM247 Lymphadenitis
MASSES,	CM326 Lymphadenopathy or palpable mass or "can feel mass".
SWELLINGS	CM327 Swelling / edema
NEURO-	CM328 Headache as a presenting sign/symptom of the index cancer
MUSCULAR	CM329 Diziness
& MENTAL	CM330 Eye / ophthalmic symptoms & signs, e.g., blurred vision, diplopia, photophobia.
222.2	CM331 Dysmetria (improper measuring of distance or range of movement in muscular action)
}	CM338 Insomnia
	CM332 Mental changes as a presenting sign/symptom of the index cancer
	CM333 Neurologic symptoms & signs as a presenting sign/symptom of the index cancer
OTHER	CM334 Alopecia, hair loss
CHER	Orado i Androda, mai 1000

CM254 Rehabilitation care, fitting of prostheses, and adjustment of devices

	(17) UNCLASSIFIED, continued
CM259	Residual codes, unclassified
	Other: Describe

[Highest numbers as of Jan 30, 2002 are CM337 (myopia, hyperopia, astigmatism, presbyopia)], 338 Insomnia, 339 hip replacement]